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Dissanayake

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(54) **SYSTEM AND METHODS FOR USE IN DISPENSING BIOPHARMACEUTICAL MATERIALS**

(71) Applicant: **REGENERON PHARMACEUTICALS, INC.**, Rensselaer, NY (US)

(72) Inventor: **Tikiri Jean Dissanayake**, Clifton Park, NY (US)

(73) Assignee: **REGENERON PHARMACEUTICALS, INC.**, Rensselaer, NY (US)

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CPC . ***B65B 3/04*** (2013.01); ***B65B 3/003*** (2013.01); ***B65B 3/22*** (2013.01); *B65B 3/12* (2013.01)

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USPC 141/2, 18, 83, 85, 236–237, 244, 286, 141/291, 301–302, 349
See application file for complete search history.

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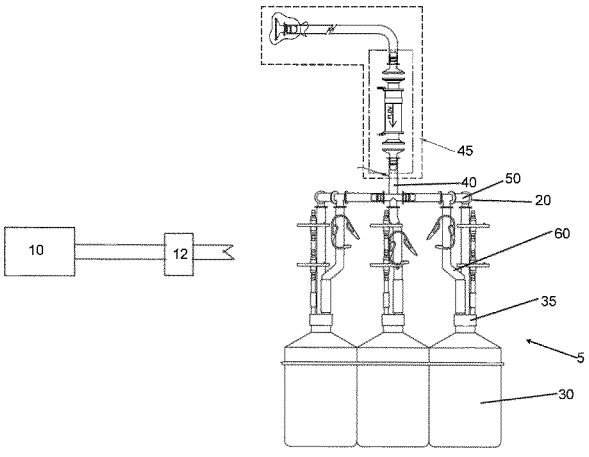
Primary Examiner — Timothy L Maust
Assistant Examiner — Timothy P Kelly
(74) *Attorney, Agent, or Firm* — Heslin Rothenberg Farley & Mesiti P.C.; Victor A. Cardona, Esq.

(57) **ABSTRACT**

A pre-sterilized system for dispensing biopharmaceutical materials includes a reservoir for holding biopharmaceutical materials coupled to a filter and distribution manifold connected to a plurality of receiving containers. The manifold includes a plurality of container conduits and a plurality of distribution conduits. The plurality of container conduits is connected to the plurality of receiving containers and supports the plurality of distribution conduits above the plurality of receiving containers to allow flow of the biopharmaceutical materials from the plurality of distribution conduits by gravity into the plurality of receiving containers. The plurality of receiving containers and the manifold are sealed relative to an ambient environment outside the manifold and the plurality of containers to inhibit contamination of the biopharmaceutical materials when the biopharmaceutical materials are inside at least one of the plurality of receiving containers and the manifold.

20 Claims, 8 Drawing Sheets



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B65B 3/22 (2006.01)
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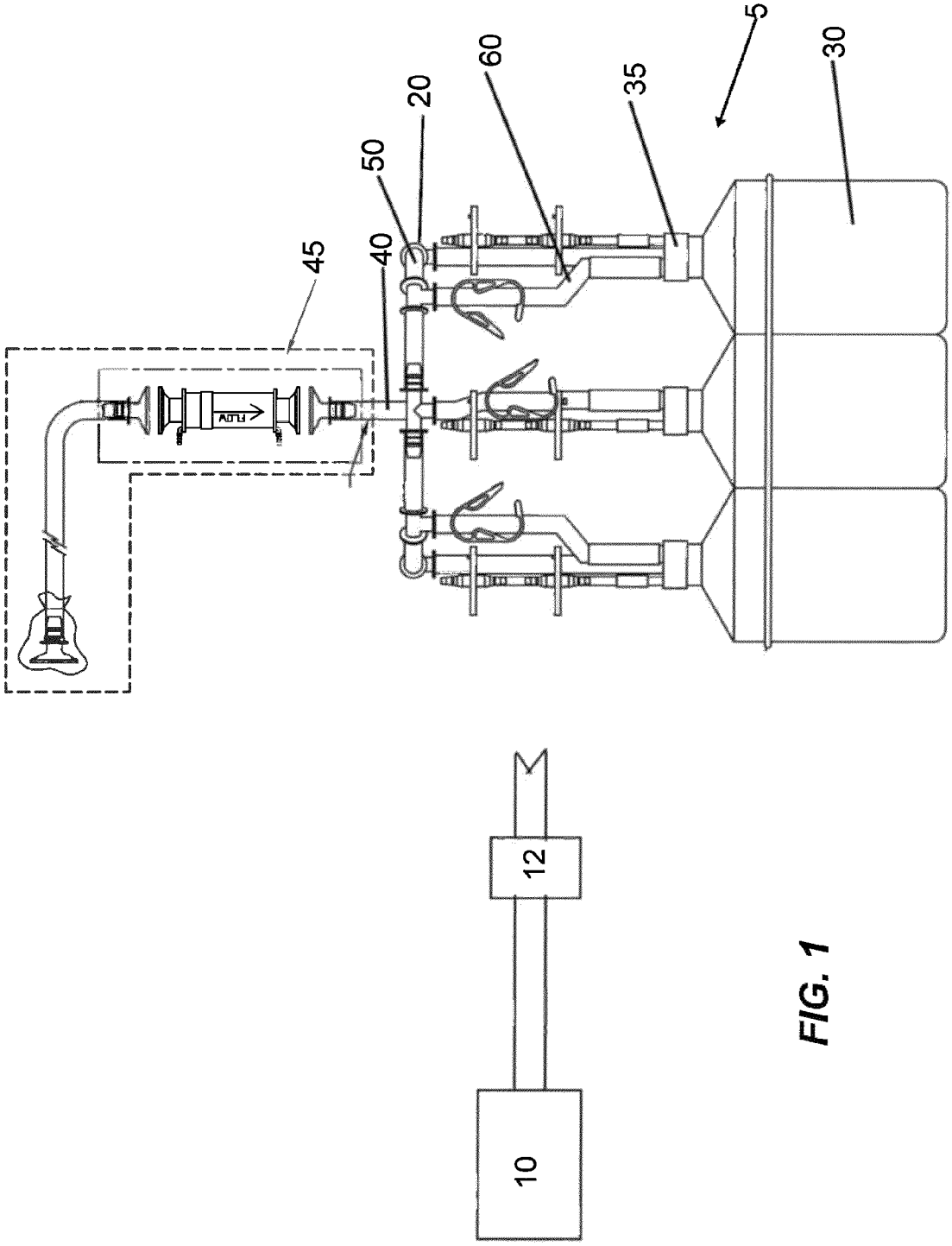

FIG. 1

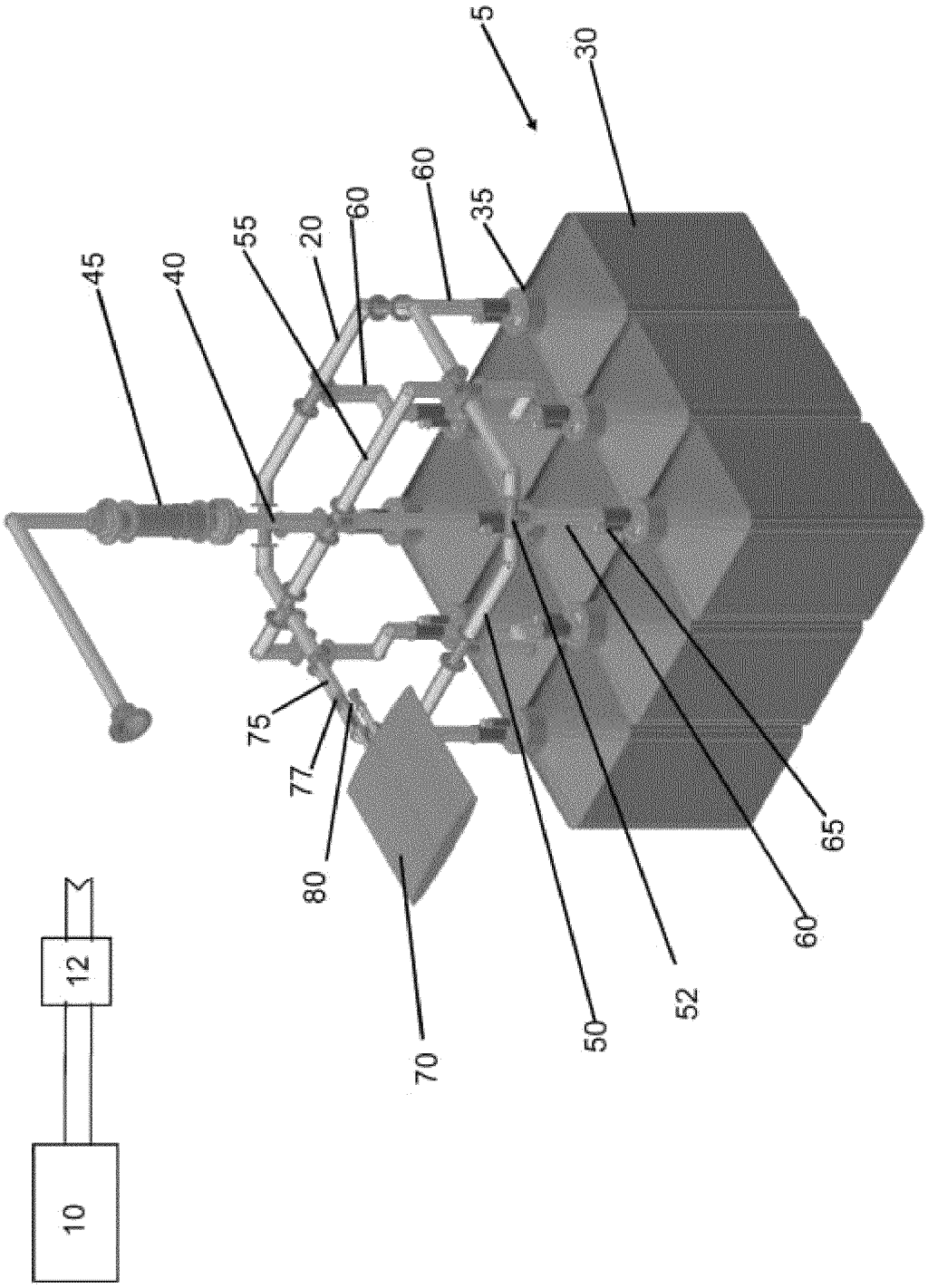

FIG. 2

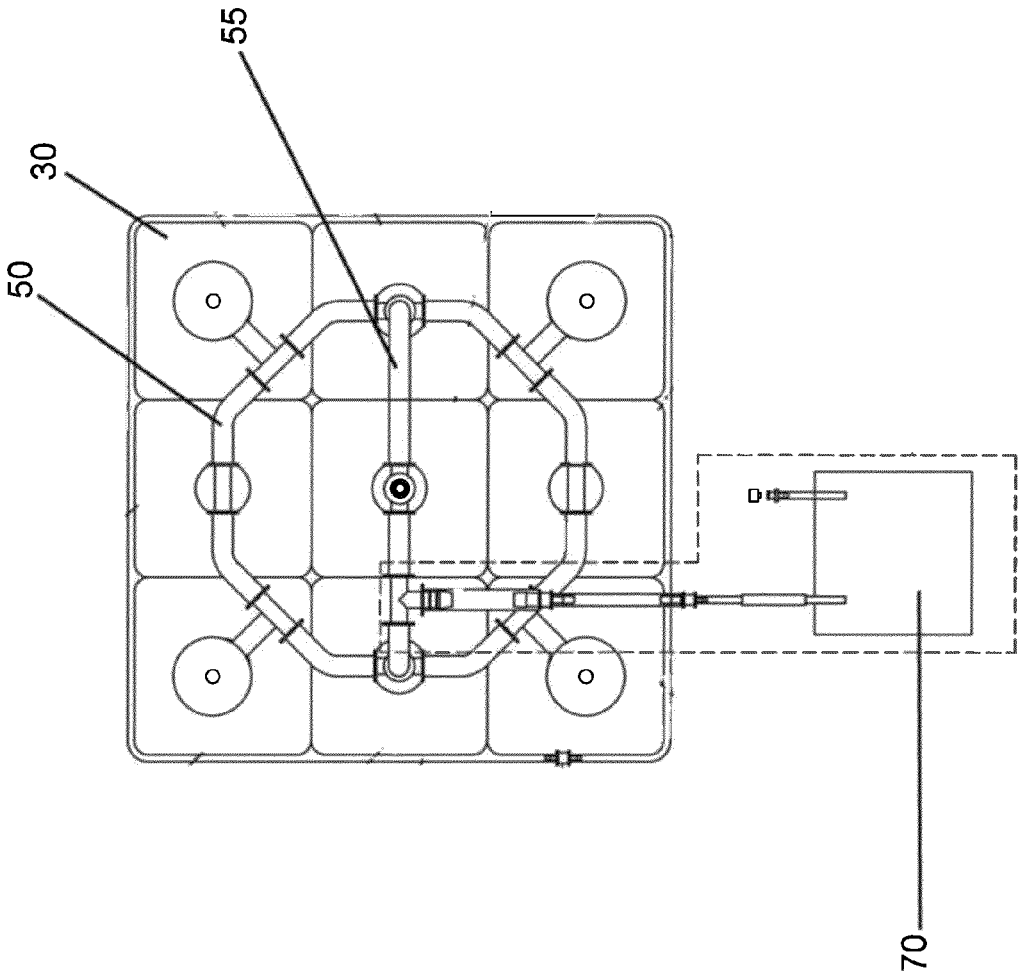

FIG. 3

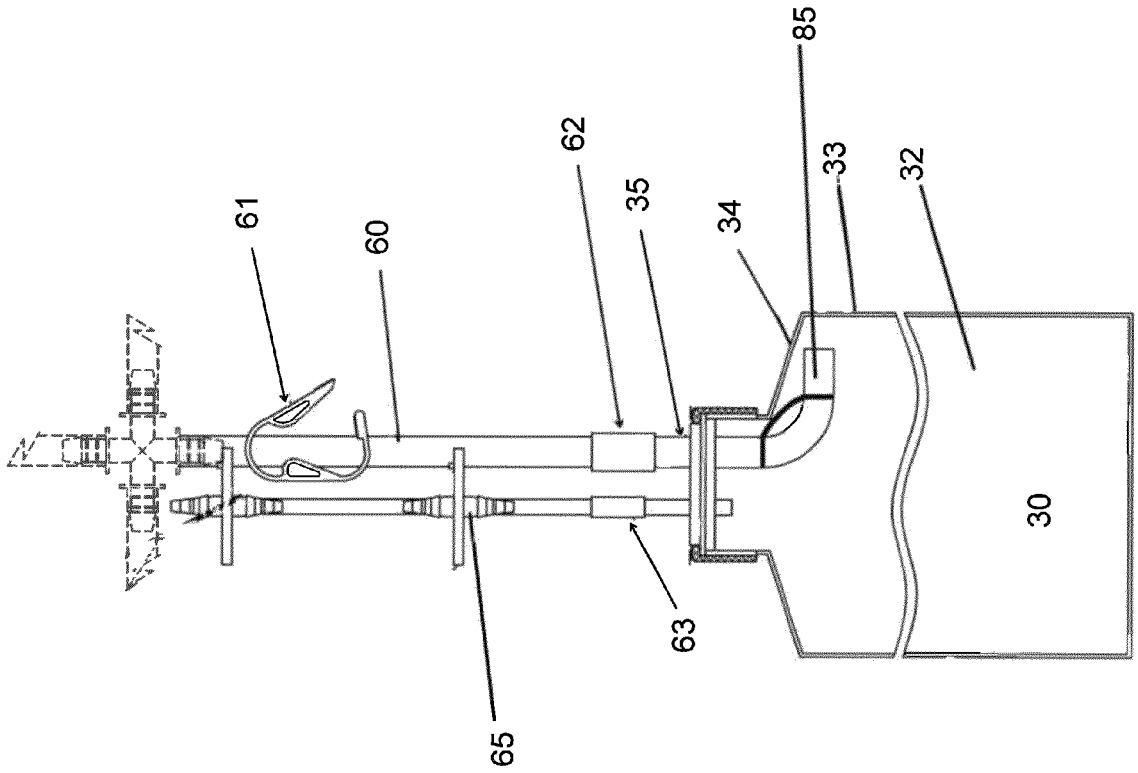

FIG. 4

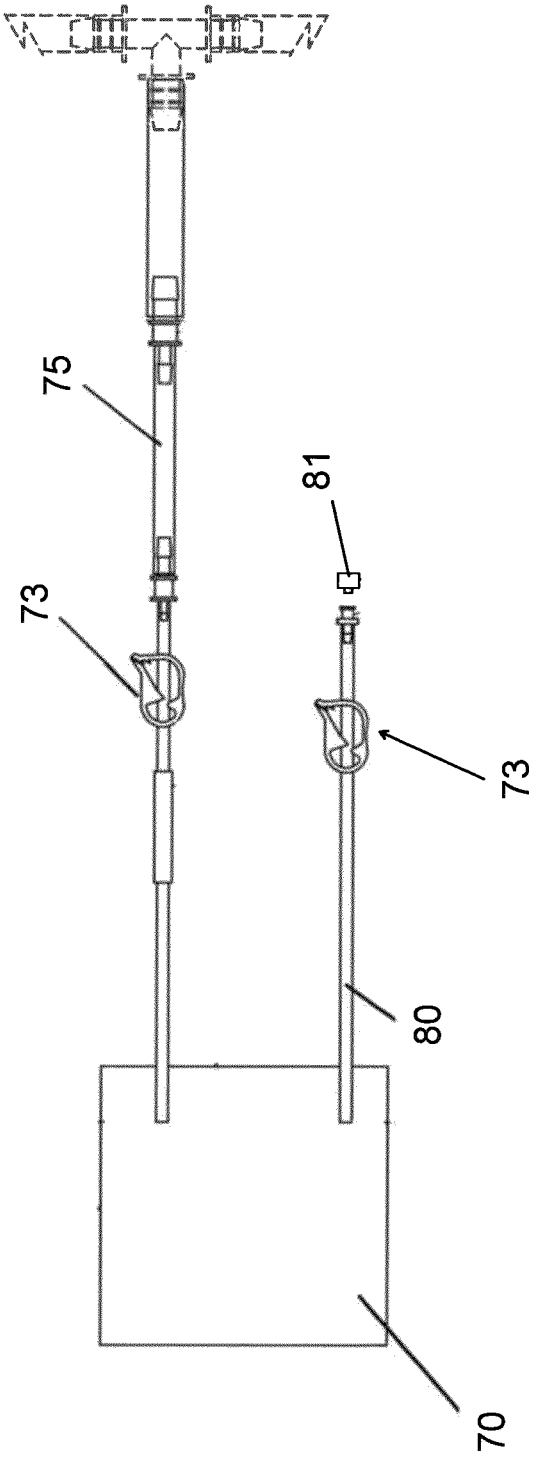

FIG. 5

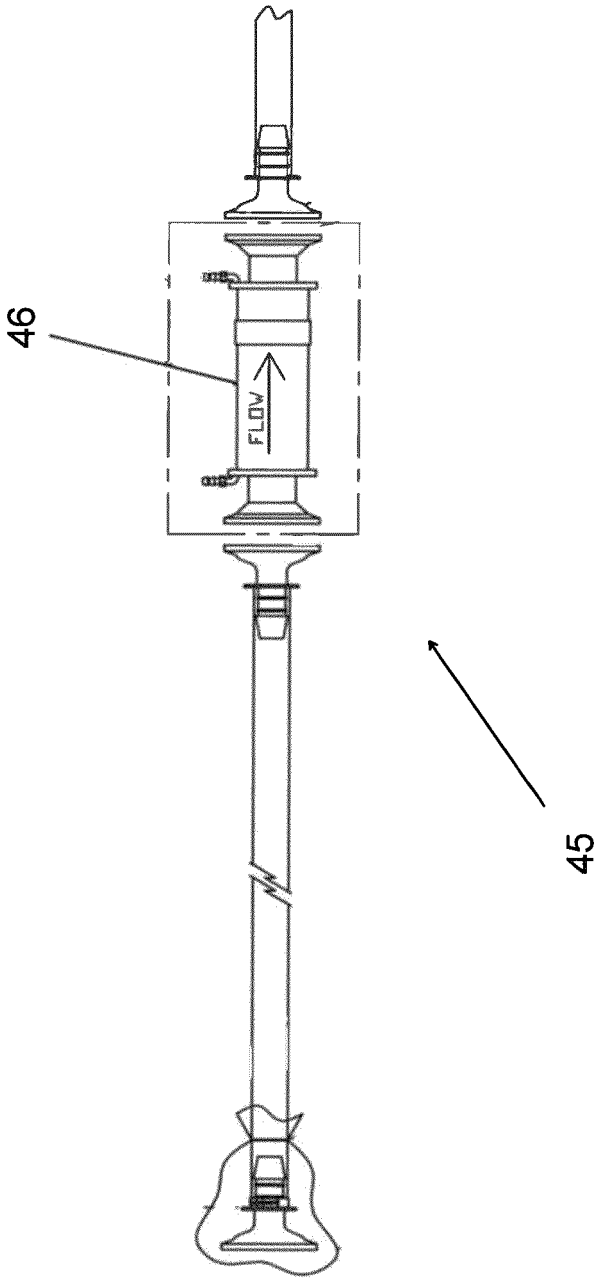

FIG. 6

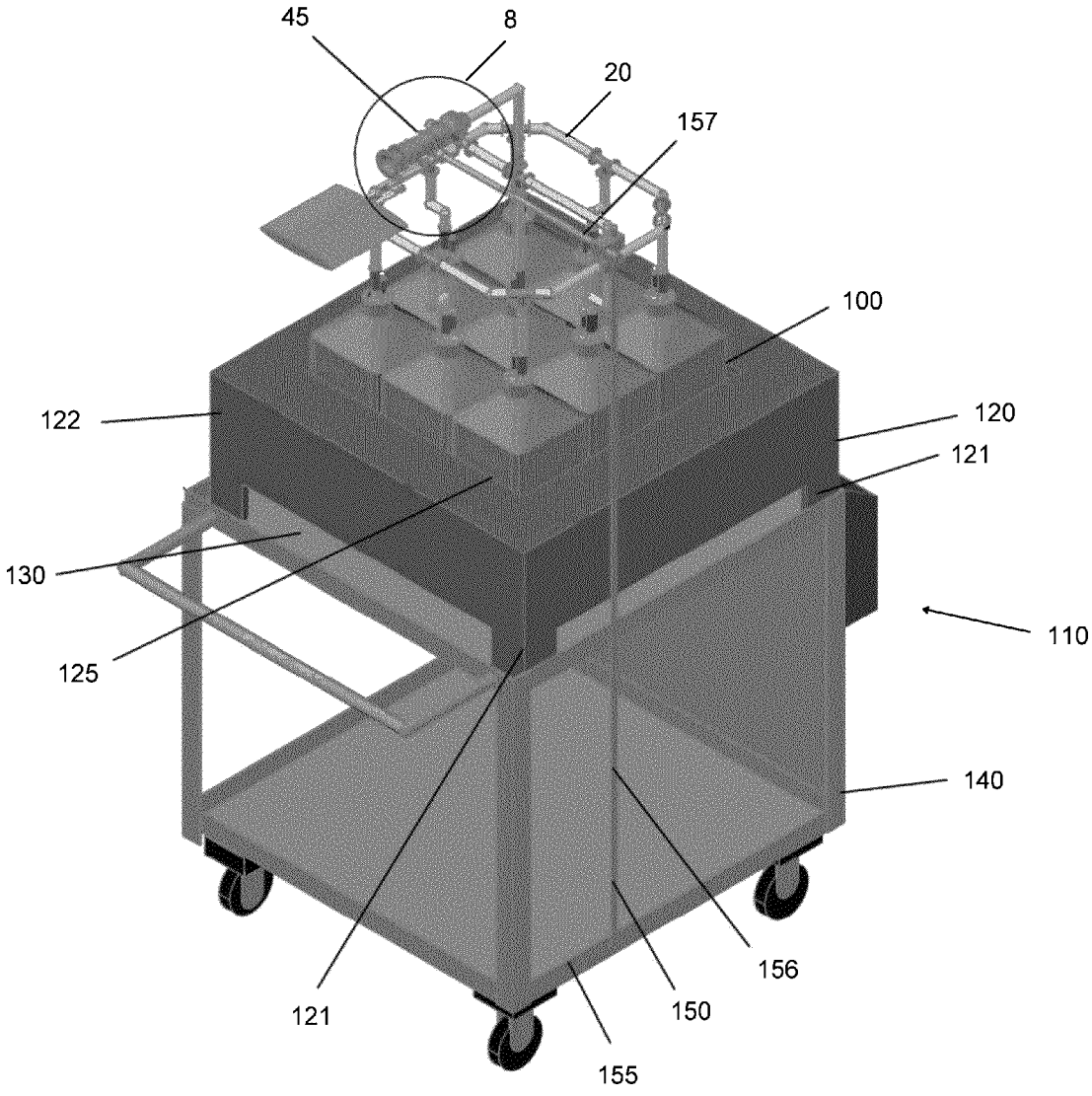

FIG. 7

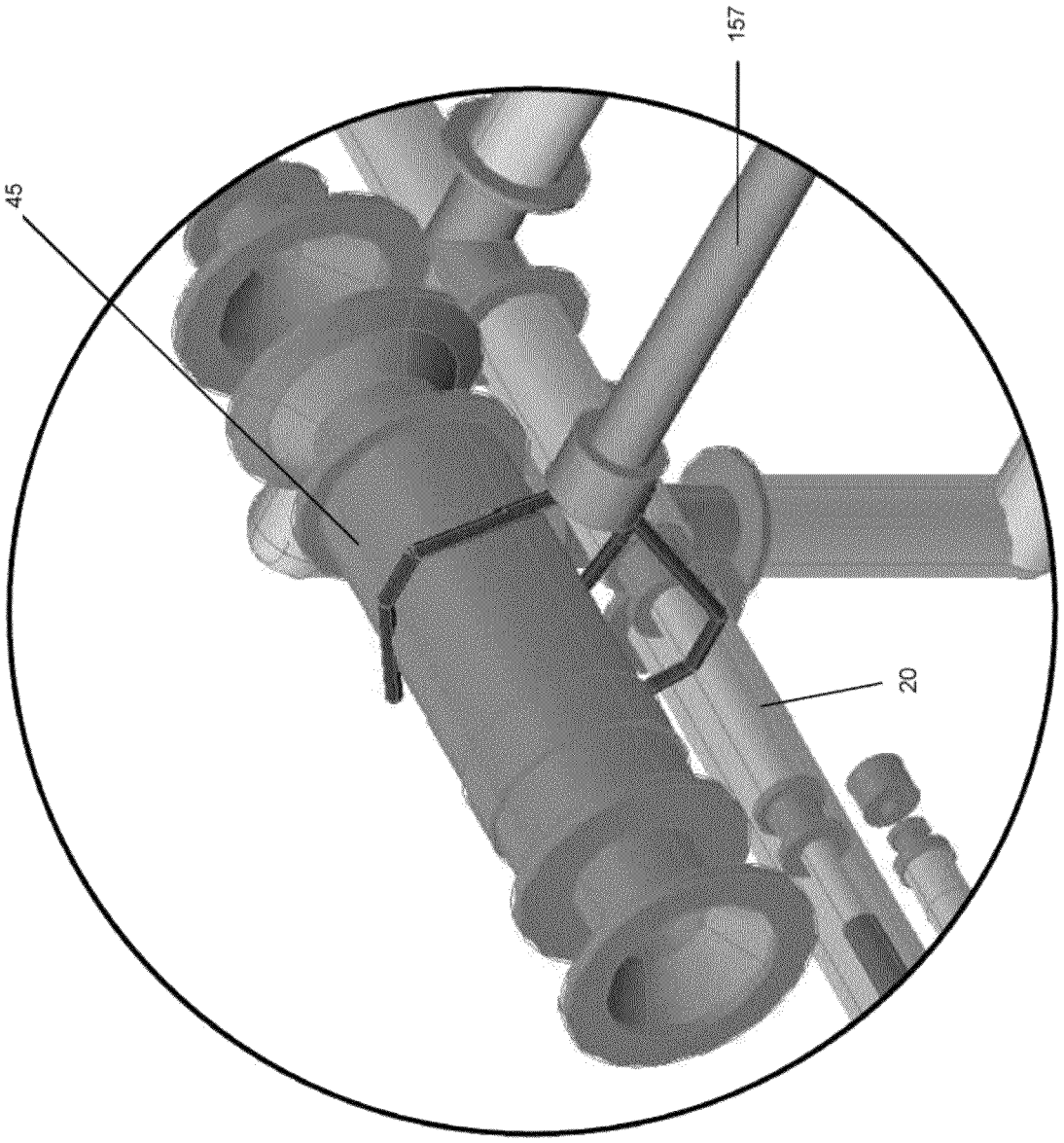

FIG. 8

SYSTEM AND METHODS FOR USE IN DISPENSING BIOPHARMACEUTICAL MATERIALS

TECHNICAL FIELD

This invention relates, in general, to biopharmaceutical materials, and more particularly to systems and methods for dispensing biopharmaceutical materials.

BACKGROUND ART

After final manufacturing, biopharmaceutical aqueous materials are often dispensed into containers to be frozen and later thawed and formulated or transported for further packaging into retail sized packaging. The dispensing occurs under sanitary conditions which involves the manual removal of the biopharmaceutical materials from a bulk reservoir (e.g., a 50 liter reservoir) into a plurality of smaller (e.g., 5 liter) containers in a clean environment which requires that workers wear appropriate clothing (e.g., sterile gowning, hoods, gloves, sleeves, etc.) and a positive pressure laminar flow hood (e.g., an ISO 5 class hood) which pushes single-pass filtered air out of the hood in order to prevent any accumulation of particulates or microbes in the environment in which the dispensing of the biopharmaceutical materials is being performed. Actual dispensing of biopharmaceutical materials is performed by removing the caps of the receiving containers within the hood, then pumping the biopharmaceutical material from a bulk container into each open bottle. Upon achieving a certain volume, each bottle is then capped and removed from the hood. A sample may be taken of the dispensed biopharmaceutical materials at some point during the process of removing the biopharmaceutical materials from the bulk reservoir and dispensing into smaller containers by dispensing the material into a separate sampling container. This sample may be tested to ensure the integrity of the biopharmaceutical materials prior to the freezing and/or final packaging thereof in smaller containers or prior to the transfer into retail-sized packaging, for example. Such sampling may be performed at various intervals during the dispensing process resulting in such samples being more or less representative of the product dispensed into the receiving containers. Further, during the filling process, monitoring of the material dispensed in an ambient environment inside the flow hood may be performed to ensure the integrity of the process.

The described dispensing requires that the biopharmaceutical materials be exposed to the uncertainties of open-air dispensing and the uncertainties of manual dispensing by a plurality of individuals required to perform such dispensing. Such uncertainties could lead to contamination of the biopharmaceutical materials and potential danger to a patient having such contaminated materials administered thereto.

Thus, there is a need for systems and methods for dispensing biopharmaceutical materials, which minimize a risk of contamination of the biopharmaceutical materials when it is transferred from a final processing container to plurality of containers for further transport thereof.

SUMMARY OF THE INVENTION

The present invention provides, in a first aspect, a presterilized (via gamma irradiation) system for dispensing biopharmaceutical materials which includes a reservoir for holding biopharmaceutical materials coupled to a distribution manifold connected to a plurality of receiving containers. The manifold includes a plurality of container conduits and a plurality of distribution conduits. The plurality of container conduits is connected to the plurality of receiving containers and supports the plurality of distribution conduits above the plurality of receiving containers to allow flow of the biopharmaceutical materials from the plurality of distribution conduits by gravity into the plurality of receiving containers. The plurality of receiving containers and the manifold are sealed relative to an ambient environment outside the manifold and the plurality of containers to inhibit contamination of the biopharmaceutical materials when the biopharmaceutical materials are inside at least one of the plurality of receiving containers and the manifold.

The present invention provides, in a second aspect, a system for dispensing biopharmaceutical materials which includes a distribution manifold coupled to a bulk reservoir for holding biopharmaceutical materials. The manifold is connected to a plurality of receiving containers to allow fluid communication between the reservoir and the plurality of receiving containers. The manifold includes a plurality of conduits connected to the plurality of receiving containers such that the manifold is self-supporting and located above the plurality of receiving containers. A sampling container is connected to the manifold to allow a flow of the biopharmaceutical materials from the reservoir to be received in the sampling container, thus providing a sample representative of the biopharmaceutical materials. The plurality of receiving containers and the manifold are sealed relative to an ambient environment outside the manifold and the plurality of containers to inhibit contamination of the biopharmaceutical materials when the biopharmaceutical materials are inside at least one of the plurality of receiving containers and the manifold.

The present invention provides, in a third aspect, a method for dispensing biopharmaceutical materials which includes flowing the biopharmaceutical materials from a bulk reservoir storing the biopharmaceutical materials to a distribution manifold coupled to a plurality of receiving container. A plurality of distribution conduits of the manifold is supported by a plurality of container conduits of the manifold connected to the plurality of receiving containers such that the plurality of distribution conduits is located above the plurality of container conduits and the plurality of receiving containers to allow a flow of the biopharmaceutical materials from the plurality of distribution conduits by gravity into the plurality of receiving containers. The plurality of receiving containers and the manifold are sealed relative to an ambient environment outside the manifold and a plurality of receiving containers to inhibit contamination of the biopharmaceutical materials received in at east one of the plurality of receiving containers and the manifold. Once the dispensing operation is completed, each bottle can be isolated and removed from the distribution manifold in a manner that is sealed relative to the ambient environment facilitating allocation and distribution.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter which is regarded as the invention is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other features, and advantages of the invention will be readily understood from the following detailed description of preferred embodiments taken in conjunction with the accompanying drawings in which:

FIG. **1** is a side view of a system for dispensing biopharmaceutical materials in accordance with the present invention;

FIG. **2** is a perspective view of the system of FIG. **1** with filters thereof removed for ease of illustration;

FIG. **3** is a top view of the system of FIG. **1**;

FIG. **4** is a side view of a portion of the system of FIG. **1** depicting a container connected to a portion of a manifold thereof;

FIG. **5** is a top view of the sampling container of the system of FIG. **1**;

FIG. **6** is a top view of a filter of the system of FIG. **1** illustrated disconnected from the manifold;

FIG. **7** is a perspective view of the system of FIG. **1** received on a cart for storage and transportation; and

FIG. **8** is an enlarged section of FIG. **7** showing a bracket of the cart holding a filter assembly of the system of FIG. **1**.

DETAILED DESCRIPTION

In accordance with the principles of the present invention, systems and methods for dispensing biopharmaceutical materials are provided.

In an exemplary embodiment depicted in FIGS. **1-6**, a system **5** for dispensing biopharmaceutical materials is shown. The system may include a bulk reservoir **10** for holding processed biopharmaceutical materials, a manifold **20** and a plurality of containers **30** connected to the manifold.

Manifold **20** includes an inlet conduit **40**, which is coupled to bulk reservoir **10** holding a quantity of processed biopharmaceutical materials (e.g., bulk drug substances or formulated drug substances) desired to be distributed into containers **30**. For example, nine containers **30** may be connected to manifold **20** for distribution of the biopharmaceutical materials into the containers as depicted in FIG. **2**. A filter assembly **45** (FIGS. **1**, **2** and **6**) may be coupled to the bulk reservoir (e.g., a 50 liter reservoir) and connected to inlet conduit **40** to inhibit any contaminants from entering containers **30** via manifold **20**.

Manifold **20** may include a plurality of distribution conduits **50** which are located above containers **30** and which receive the biopharmaceutical materials from feeder conduits **55** connected to inlet conduit **40**, wherein distribution conduits **50** may be located below feeder conduits **55** and above the containers. Distribution conduits **50** may be connected to each other in a loop or otherwise continuous shape (e.g., a modified-square with opposing corners modified to include T-shaped connectors **52** as depicted in FIG. **2**) or otherwise such that all of distribution conduits **50** are at about the same height relative to each other and the containers and the distribution conduits may all be in fluid communication with each other. Each of the containers is connected to a container discharge conduit **60** of manifold **20** with container discharge conduit **60** connected to one of distribution conduits **50** via a T-connector or other connector which allows flow throughout the manifold and flow into each container simultaneously.

Manifold **20** connected to the receiving containers may be self-standing such that the distribution conduits **50** are supported by container conduits **60** connected to containers **30**. Feeder conduits **55**, conduit **40** and filter assembly **45** may also be supported. The various conduits of the manifold connected to the containers are thus configured (e.g., shaped, dimensioned, and having sufficient stiffness) to be connected to one another such that the manifold is self-supporting and remains standing on top of the containers during a dispensing operation such that it is free-draining (e.g., by gravity) in order to maximize the amount of biopharmaceutical materials which are dispensed from the reservoir **10** to receiving containers **30**.

A sampling container **70** may be in fluid communication with distribution conduits **50** such that a flow of the biopharmaceutical materials received from reservoir **10** may be received in sampling container **70** as depicted in FIGS. **1**, **2** and **5**, for example. Once the sample has been taken into container **70**, it may be isolated and removed from the feeder conduit **55** in a manner that is sealed relative to the ambient environment, facilitating allocation and distribution. The biopharmaceutical materials held in sampling container **70** may later be analyzed to confirm the quality of the biopharmaceutical materials held in containers **30** by an analysis of the biopharmaceutical materials held in sampling container **70**. By analyzing the contents of sampling container an analysis of each of the containers **30** may be avoided. Sampling container **70** may be connected to feeder conduits **55** via a sampling container conduit **75**. Alternatively, sampling container **70** could be connected to another portion of manifold **20** via such a sampling container conduit. An outlet **80** of sampling container **70** having a plug **81** may be utilized to allow air to escape from sampling container **70** or to allow sampling of the biopharmaceutical materials held therein after sampling container **70** is disconnected from a portion of sampling container conduit **75**. A quick seal connector **77** may be located on conduit **75** and may seal a side of the seal connected with sampling container **70** and a second side of the quick seal, which remains with sampling container conduit **75** when opposite portions of the seal are separated. Such a quick seal may be an aseptic-type seal which allows opposite portions of the seal to be disconnected relative to one another sealing both disconnected portions to inhibit contamination. Also, ratchet clamps **73**, or other means of selectively preventing and allowing flow of the biopharmaceutical materials as desired, may be located on sampling container conduit **75** and outlet **80** to allow flow of the biopharmaceutical materials into and/or out of sampling container **70** as desired during a dispensing operation. In another example, the biopharmaceutical materials could flow through the sampling container prior to the biopharmaceutical materials entering the container conduits, the feeder conduit, and/or the containers.

Similarly, each of container conduits **60** may include a quick seal **62**. Also, each of containers **30** includes a container sterilizing grade hydrophobic filter assembly **65** (e.g., a 0.22 μm porosity filter) which allows air to vacate the containers when biopharmaceutical materials enters therein while inhibiting contamination from entering such containers. Quick seal **62** may be utilized to allow filter assembly **65** to be removed while maintaining an appropriate sealed environment for one of containers **30** attached to the corresponding container conduit. As depicted in FIG. **4**, each of container conduits **60** may also include an extension **85** which extends from the container conduit into an interior **32** of container **30** and directs the biopharmaceutical materials against a vertical wall **33** and/or a top surface **34** of container **30** to allow the biopharmaceutical materials to flow down the wall into the container and to inhibit foaming or air entrainment in the biopharmaceutical materials which could lead to degradation (e.g., aggregation) of the biopharmaceutical materials, which is undesirable and may cause biopharmaceutical materials to be less effective or ineffective relative to particular desired pharmaceutical properties.

Each of container conduits **60** may also include a ratchet clamp **61**, or other means of releasably preventing flow into or out of container(s) **30** during the dispensing of the biopharmaceutical materials from reservoir **10** into containers **30**. Also, each of container conduits **60** may extend from distribution conduits **50** at different angles relative to each other

and the containers. For example, as depicted in FIG. **2**, the container conduits connecting distribution conduits **50** to the containers directly below filter assembly **45** and on opposite corners of the manifold may extend vertically from distribution conduits **50** toward the containers while the container conduits connecting to the containers in an interior position may be angled or extend vertically, horizontally and vertically to the container. Further, each of containers **30** may include a stopper **35** which allows a container conduit **60** of the container conduits and container filter assembly **65** to extend therethrough while inhibiting any contamination from entering the container.

As depicted in FIG. **6**, filter assembly **45** connected to conduit **40** and coupled to reservoir **10** may include an in-line sterilizing grade hydrophilic filter **46** (e.g., a filter having a porosity≤0.2 μm) which inhibits the passage of contaminants in the direction of manifold **20** through conduit **40**. A non-contacting pump **12** (e.g., a peristaltic pump) may be located between reservoir **10** and filter assembly **45** and may pump the biopharmaceutical materials from reservoir **10** toward manifold **20**. FIG. **1** depicts reservoir **10** and pump **12** separated from filter assembly **45**, but these components could be connected to each other prior to a dispensing operation using a Tri-Clamp-type sanitary connector, for example. In another example, conduit **40** may be coupled to a bulk reservoir (e.g., reservoir **10**) without a filter between the reservoir and the conduit. In particular, conduit **40** could be connected to such a reservoir by a sterile connecting device such that a filter utilized to prevent degradation caused by a sanitary connection between the conduit and the reservoir would not be necessary, as would be understood by one of ordinary skill in the art. Specifically, use of a sterile connecter would prevent the introduction of contaminants into conduit **10** and thus system **5**.

In one example, a method for dispensing biopharmaceutical materials includes pumping the biopharmaceutical materials from reservoir **10** by pump **12** through filter assembly **45** to manifold **20**. The biopharmaceutical materials may enter feeder conduits **55** and flow therefrom into distribution conduits **50** and containers **30**. A user may open and close various clamps (e.g., ratchet clamp **61**, ratchet clamp **73**) on distribution conduits **50** and container conduits **60** to direct the biopharmaceutical materials which may flow by gravity or the force of the pump from feeder conduits **55** into the various containers by the opening and closing of such clamps. The biopharmaceutical materials may flow into the containers through extensions **85** against wall **33** to minimize any potential degradation of the biopharmaceutical materials entering the containers. During the distribution of biopharmaceutical materials into the various containers, one of ratchet clamps **73** may be opened to allow flow of the biopharmaceutical materials into sampling container **70** followed by closing of the ratchet when the container is full. Quick seals on each of container conduits **60** may be sealed and a portion of each seal separated from manifold **20** to allow removal of the containers therefrom and transportation of the containers to an appropriate facility for further processing, e.g., freezing, formulation, or packaging thereof into retail size containers. Similarly, quick seal **77** on sampling container conduit may be sealed and separated.

The conduits described above (e.g., distribution conduits **50**, conduit **40**, feeder conduits **55**, and container conduits **60**) may all be silicone tubing or formed of a material which does not degrade in the presence of biopharmaceutical materials or otherwise contaminate such materials. The biopharmaceutical materials could be but would not be limited to, any aqueous cell culture medias, chromatography buffers or therapeutic molecules suspended in specially formulated solutions. The containers (e.g., containers **30**) may be 5 liter polycarbonate biotainers or any other container of various sizes formed of a material or having an interior which inhibits degradation or contamination of biopharmaceutical materials held therein. The containers are preferably rigid or semi-rigid such that they are self-supporting and retain their shape when holding biopharmaceutical materials. Such containers could also be connected to one another (e.g., using a propylene connector such that the containers remain abutting one another during the dispensing of the biopharmaceutical materials. Various portions (e.g., distribution conduit portions **55**, conduit **40**, feeder conduit **55**, container conduit **60**) of the manifold may also be connected together utilizing connectors (e.g., T-shaped connectors) which may be formed of animal derivative free polypropylene T-shaped connectors or other connectors configured (e.g., shaped and dimensioned) to connect the conduits (e.g., distribution conduit portions **55**, conduit **40** feeder conduit **55**, container conduit **60**) to one another such that the biopharmaceutical materials are sealed therein and to avoid environmental contamination.

As depicted in FIG. **7**, containers **30** of system **5** may be received in a cavity **100** of a system **110** for transporting and holding system **5**. System **110** may include a container holder **120** having an interior surface **125** bounding cavity **100** and forming a protective barrier around containers **30**. Container holder **120** may be formed of polypropylene or another material configured to hold containers **30** together and inhibit damage to the containers by any object that could otherwise bump or pierce the containers. Container holder **120** may be received on a top surface **130** of a cart **140** for transporting system **5**. Cart **140** may be formed of stainless steel and top surface **130** could be 30 inches by 30 inches and have a height of 39 inches to surface **130**. Cart **140** may also include a supporting bracket **150** which extends vertically and horizontally from a bottom shelf **155** of cart **140**. Bracket **150** may support and hold filter assembly **45** above manifold **20** as depicted in FIGS. **7** and **8**. Bracket **150** may include a vertical component **156** and a horizontal component **157** to facilitate locating bracket **150** above manifold **20**.

In another example, a scale (not shown) could be received on top surface **130** and could have containers **30** thereon such that the scale could measure the weight of the containers. As filling of the containers is performed the scale could measure a weight of the containers. Such weight could be used to determine the volume of the biopharmaceutical materials in the containers as the filling of the containers proceeds and whether more biopharmaceutical materials should flow into the containers. Container holder **120** would also surround and protect containers **30** as described above while avoiding contact with the scale or any portion of the scale which would affect the measurement of the weight of the containers received on the scale. As depicted in FIG. **7**, container holder **120** could include legs **121** which would allow a main portion **122** to be raised above and not contact a scale received on top surface **130** while still surrounding the containers. In a further example, multiple scales could be received on top surface **130** to allow an individual measurement of the weight of individual containers or the measurement of the weight of groups of containers together. All materials used in system **110** are suitable for clean room usage and can withstand the chemicals utilized for standard cleaning procedures in such a clean room.

While the invention has been depicted and described in detail herein, it will be apparent to those skilled in the relevant art that various modifications additions, substitutions and the like can be made without departing from the spirit of the

invention and these are therefore considered to be within the scope of the invention as defined in the following claims.

The invention claimed is:

1. A system for dispensing biopharmaceutical materials, the system comprising:

a plurality of receiving containers;

a distribution manifold connected to the plurality of receiving containers;

a pre-sterilized filter;

a reservoir for holding biopharmaceutical materials connected to the pre-sterilized filter and the distribution manifold, the filter located between said reservoir and said manifold;

said manifold comprising a plurality of container conduits and a plurality of distribution conduits, said plurality of distribution conduits connected to each other to form a continuous shape such that interiors of said plurality of distribution conduits are in fluid communication with each other and are at about a same height relative to each other;

said plurality of container conduits connected to said plurality of receiving containers and supporting said plurality of distribution conduits above said plurality of receiving containers to allow flow of the biopharmaceutical materials from said plurality of distribution conduits by gravity into said plurality of receiving containers; and

said plurality of receiving containers and said manifold sealed relative to an ambient environment outside said manifold and said plurality of containers to inhibit contamination of the biopharmaceutical materials when the biopharmaceutical materials are inside at least one of said plurality of receiving containers or said manifold.

2. The system of claim **1** further comprising a sampling container connected to said manifold to allow a flow of the biopharmaceutical materials from said manifold into said sampling container.

3. The system of claim **2** further comprising a sealing connector to allow said sampling container to be sealingly detached from said manifold.

4. The system of claim **2** wherein said sampling container is coupled to said reservoir and said plurality of receiving containers such that the biopharmaceutical materials flows from said reservoir through said sampling container to said plurality of receiving containers.

5. The system of claim **1** further comprising a sampling container in fluid communication with said reservoir and said plurality of receiving containers to allow a flow of the biopharmaceutical materials from said reservoir to said plurality of receiving containers to be received in said sampling container.

6. The system of claim **1** wherein the plurality of container conduits extend into said plurality of receiving containers.

7. The system of claim **6** wherein a first container conduit of the plurality of container conduits comprises an outlet directed against a wall of a first receiving container of the plurality of receiving containers to inhibit foaming of the biopharmaceutical materials when the biopharmaceutical materials flow into the first receiving container.

8. The system of claim **6** wherein a first container conduit of the plurality of container conduits extends into a first container of said plurality of receiving containers, said first container conduit comprising a sealable connector and further comprising an exit port allowing a flow of air from said first container, said exit port comprising a second sealable connector.

9. The system of claim **1** further comprising a plurality of exit ports having filters thereon to allow a flow of air from said plurality of receiving containers when the biopharmaceutical materials flows into the plurality of receiving containers, the filters inhibiting contamination of the biopharmaceutical materials.

10. The system of claim **1** further comprising a pump coupled to said reservoir and said manifold for pumping the biopharmaceutical materials from the reservoir to said manifold.

11. The system of claim **1** wherein said manifold further comprises a plurality of feeder conduits.

12. A system for dispensing biopharmaceutical materials, the system comprising:

a reservoir for holding biopharmaceutical materials;

a distribution manifold coupled to the reservoir;

a plurality of receiving containers;

said manifold connected to the plurality of receiving containers to allow fluid communication between said reservoir and said plurality of receiving containers;

said manifold comprising a plurality of container conduits connected to said plurality of receiving containers such that said manifold is self-supporting and located above said plurality of receiving containers, and a plurality of distribution conduits connected to each other to form a continuous shape such that interiors of said plurality of distribution conduits are in fluid communication with each other and are at about a same height relative to each other, said plurality of distribution conduits are supported by the plurality of container conduits;

a sampling container directly connected to a distribution conduit of the plurality of distribution conduits of said manifold to allow a flow of the biopharmaceutical materials from said reservoir to be received in said sampling container; and

said plurality of receiving containers and said manifold sealed relative to an ambient environment outside said manifold and said plurality of containers to inhibit contamination of the biopharmaceutical materials when the biopharmaceutical materials are inside at least one of said plurality of receiving containers and said manifold.

13. A method for dispensing biopharmaceutical materials comprising:

flowing the biopharmaceutical materials from a reservoir storing the biopharmaceutical materials to a distribution manifold coupled to a plurality of receiving containers;

supporting a plurality of distribution conduits of the manifold by a plurality of container conduits of the manifold connected to the plurality of receiving containers such that the plurality of distribution conduits is located above the plurality of container conduits and the plurality of receiving containers to allow a flow of the biopharmaceutical materials from the plurality of distribution conduits by gravity into the plurality of receiving containers;

the plurality of distribution conduits connected to each other to form a continuous shape such that interiors of the plurality of distribution conduits are in fluid communication with each other and are at about a same height relative to each other; and

sealing the plurality of receiving containers and the manifold relative to an ambient environment outside the manifold and the plurality of receiving containers to inhibit contamination of the biopharmaceutical materials received in at least one of the plurality of receiving containers and the manifold.

14. The method of claim **13** further comprising:

flowing the biopharmaceutical materials from the manifold to a sampling container connected to the manifold and sealing the sampling container relative to the manifold.

15. The method of claim **13** wherein a first container conduit of the plurality of container conduits comprises an outlet directed against a wall of a first-receiving container of the plurality of receiving containers and flowing the biopharmaceutical materials through the outlet to inhibit aggregation of the biopharmaceutical materials flowing into the first-receiving container.

16. The method of claim **13** further comprising flowing the biopharmaceutical material into the plurality of receiving containers by a force of gravity alone.

17. The method of claim **13** further comprising pumping the biopharmaceutical materials from the reservoir to the manifold using a pump.

18. The system of claim **1** wherein said continuous shape comprises a nonlinear, non-terminating shape.

19. The system of claim **18** wherein said continuous shape comprises a loop.

20. The system of claim **18** wherein said continuous shape comprises a modified square.

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